

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: BOSTON SCIENTIFIC CORP.
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION

MDL No. 2326

THIS DOCUMENT RELATES TO THE CASES ON THE ATTACHED EXHIBIT A

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Dr. Dionysios Veronikis, M.D.)

Pending in *In re Boston Scientific Corp.*, No. 2:12-md-2326, MDL 2326, is the Defendant's Motion to Limit the Opinions and Testimony of Dionysios Veronikis, M.D. filed by Boston Scientific Corporation ("BSC"). [ECF No. 4807]. The Motion is now ripe for consideration because the briefing is complete. As set forth below, BSC's Motion is **GRANTED in part** and **DENIED in part**.

I. Background

This group of cases resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation ("MDL") concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the six remaining MDLs, there are more than 17,000 cases currently pending, approximately 3800 of which are in the BSC MDL, MDL No. 2326.

In an effort to manage the massive BSC MDL efficiently and effectively, I decided to conduct pretrial discovery and motions practice on an individualized basis. To this end, I selected certain cases to become part of a "wave" of cases to be prepared for trial and, if necessary, remanded.

Upon the creation of a wave, I enter a docket control order subjecting each active case in the wave to the same scheduling deadlines, rules regarding motion practice, and limitations on discovery. *See, e.g.*, Pretrial Order (“PTO”) # 165, *In re Bos. Sci. Corp. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-02326, June 21, 2017, <http://www.wvsc.uscourts.gov/MDL/boston/orders.html>. Included among the discovery rules imposed by the court is the obligation of the parties to file *Daubert* motions seeking to limit or exclude the testimony of general causation experts in the main MDL, MDL 2326.

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if it will “help the trier of fact to understand the evidence or to determine a fact in issue” and (1) is “based upon sufficient facts or data” and (2) is “the product of reliable principles and methods,” which (3) has been reliably applied “to the facts of the case.” Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it “rests on a reliable foundation and is relevant.” *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The proponent of expert testimony does not have the burden to “prove” anything. However, he or she must “come forward with evidence from which the court can determine that the proffered testimony is properly admissible.” *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court’s role as gatekeeper is an important one. “[E]xpert witnesses have the potential to be both powerful and quite misleading”; the court must “ensure that any and all scientific testimony . . . is not only relevant, but reliable.” *Cooper v.*

Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 588, 595; *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). I “need not determine that the proffered expert testimony is irrefutable or certainly correct. As with all other admissible evidence, expert testimony is subject to testing by ‘[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.’” *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (alteration in original) (citation omitted) (quoting *Daubert*, 509 U.S. at 596); see also *Md. Cas. Co.*, 137 F.3d at 783 (“All *Daubert* demands is that the trial judge make a ‘preliminary assessment’ of whether the proffered testimony is both reliable . . . and helpful.”).

Daubert mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory “can be (and has been) tested”; (2) whether the theory “has been subjected to peer review and publication”; (3) the “known or potential rate of error”; (4) the “existence and maintenance of standards controlling the technique’s operation”; and (5) whether the technique has achieved “general acceptance” in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

Despite these factors, “[t]he inquiry to be undertaken by the district court is ‘a flexible one’ focusing on the ‘principles and methodology’ employed by the expert, not on the conclusions reached.” *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); see also *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) (“We

agree with the Solicitor General that “[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert’s particular expertise, and the subject of his testimony.” (alteration in original)); *see also Crisp*, 324 F.3d at 266 (noting “that testing of reliability should be flexible and that *Daubert*’s five factors neither necessarily nor exclusively apply to every expert”).

With respect to relevancy, *Daubert* also explains:

Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of “fit.” “Fit” is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702’s “helpfulness” standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591-92 (citations and internal quotation marks omitted).

III. Analysis

Dr. Veronikis is a urogynecologist who is board-certified in female pelvic medicine, reconstructive surgery, and obstetrics and gynecology. In his practice, he has revised or removed over 1100 vaginal mesh products, including vaginal transvaginal mesh slings and prolapse mesh kits.

A. BSC’s Knowledge or State of Mind

First, BSC argues that I should preclude Dr. Veronikis from testifying as to BSC’s knowledge or state of mind. I agree; experts may not testify about what other parties did or did not know. However, to the extent BSC seeks to exclude Dr. Veronikis’s testimony about factual issues or the knowledge of the medical

community in general, I disagree. Expert witnesses may properly offer opinions on these topics. Therefore, BSC's Motion is **GRANTED** to the extent that it seeks to exclude evidence regarding BSC's knowledge or intent.

B. Design and Testing

Second, BSC challenges Dr. Veronikis's opinions regarding a safer alternative design for the Solyx and the design process and testing for the mesh product.

As to design, Dr. Veronikis opines as follows:

BSC was offered a lightweight mesh in 2008, which would have also been a safer alternative design to the Advantage mesh used in Solyx, in that a lighter weight mesh has less surface area leading to reduced scar plate formation, reduced inflammation and thus fewer complications such as chronic pain and chronic dyspareunia.

Veronikis Report 3–4 (footnotes omitted). BSC challenges Dr. Veronikis's opinion that a safer alternative design existed at the time the Solyx was marketed. Dr. Veronikis's opinion on this issue was based upon a reliable methodology—relying on internal BSC documents, clinical experience, and review of scientific literature—and he is qualified from his experience, knowledge, and skill to offer such opinions. Accordingly, BSC's Motion on this issue is **DENIED**.

BSC also challenges Dr. Veronikis's qualification to offer opinions on design process and testing. Experience as a practicing urogynecologist alone does not translate into experience with or knowledge about the appropriate testing a medical device manufacturer should undertake when preparing a product for the market. Because Dr. Veronikis lacks the qualifications required by Rule 702, any opinion

concerning BSC's product testing, or lack thereof, is **EXCLUDED**. BSC's Motion on this issue is **GRANTED**.

C. Adequacy of Warnings

Third, BSC argues that Dr. Veronikis's opinions regarding the inadequacy of the warnings contained in the Solyx's and Prefyx's Directions for Use ("DFU") are unreliable. The court agrees. In his deposition, Dr. Veronikis states that he did not review the DFUs while he was preparing his report. Veronikis Dep. 11:24–12:11, Nov. 24, 2014. Offering opinions on the adequacy of a device's DFU without examining them for the expert report is not a reliable methodology. Dr. Veronikis's failure to review the Solyx's or Prefyx's DFU demonstrates that his opinions on the issue are not based upon the very facts needed to form the opinion in the first place. Accordingly, Dr. Veronikis's opinions on this issue are **EXCLUDED**, and BSC's Motion on this point is **GRANTED**.

D. Material Safety Data Sheets ("MSDS")

Fourth, BSC argues that Dr. Veronikis is not qualified to offer opinions on the MSDS for polypropylene resin, due to his lack of experience or familiarity with MSDSs. I agree that Dr. Veronikis lacks the requisite knowledge, skill, experience, education, or training necessary to qualify him as an expert on MSDS issues. Thus, to the extent BSC seeks to prevent Dr. Veronikis from opining on the adequacy or relevancy of the MSDS, its Motion is **GRANTED**.

However, the particular opinion that BSC seeks to exclude is that "the polypropylene mesh material was never intended to be implanted permanently in

human bodies, as stated in the Material Safety Data Sheet for the Marlex polypropylene resin used by BSC in its products.” In this statement, Dr. Veronikis does not comment on the adequacy or relevancy of the MSDS, but merely relies on it in forming his opinion that “the polypropylene mesh material was never intended to be implanted permanently in human bodies.” Thus, to the extent BSC seeks to exclude this statement, its Motion is **DENIED**.

E. Legal Conclusions

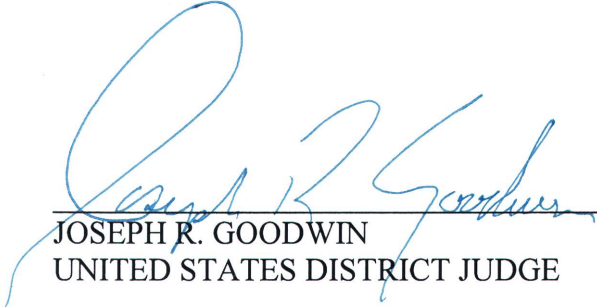
Finally, BSC contends that Dr. Veronikis seeks to offer testimony constituting various legal opinions. Throughout these MDLs, the court has prohibited the parties from using experts to usurp the jury’s fact-finding function by allowing testimony of this type, and I do the same here. *See, e.g., In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *see also, e.g., United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) (“[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.”). Additionally, an expert may not offer expert testimony using “legal terms of art,” such as “defective,” “safer alternative design,” or “proximate cause.” *See Perez v. Townsend Eng’g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008). Thus, to the extent that Dr. Veronikis’s opinions constitute legal conclusions, those opinions are **EXCLUDED**. BSC’s Motion is **GRANTED** on this point.

IV. Conclusion

To summarize, BSC’s *Daubert* Motion concerning Dr. Veronikis [ECF No. 4807] is **GRANTED in part** and **DENIED in part**.

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2326 and all individual cases listed on the attached Exhibit A. The court further **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: May 29, 2018



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

EXHIBIT A

Case Number	Case Name
2:17-cv-00047	Long v. Boston Scientific Corporation
2:17-cv-00049	Parker et al v. Boston Scientific Corporation
2:17-cv-00294	Grigg v. Boston Scientific Corporation
2:17-cv-00304	Martinez v. Boston Scientific Corporation
2:17-cv-00307	Michael v. Boston Scientific Corporation
2:17-cv-00314	Newton v. Boston Scientific Corporation
2:17-cv-00315	Norris v. Boston Scientific Corporation
2:17-cv-00317	Norris v. Boston Scientific Corporation
2:17-cv-00318	Osborn v. Boston Scientific Corporation
2:17-cv-00325	Pick v. Boston Scientific Corporation
2:17-cv-00528	Sustaita v. Boston Scientific Corporation
2:17-cv-00534	Notestine v. Boston Scientific Corporation
2:17-cv-00536	Sutiff v. Boston Scientific Corporation
2:17-cv-00568	Mahnke v. Boston Scientific Corporation
2:17-cv-00701	Babcock v. Boston Scientific Corporation
2:17-cv-01074	Dembski v. Boston Scientific Corporation
2:17-cv-01098	Zeiter v. Boston Scientific Corporation

2:17-cv-01109	Herbert et al v. Boston Scientific Corporation
2:17-cv-01241	Tigner v. Boston Scientific Corporation
2:17-cv-01242	Evans v. Boston Scientific Corporation
2:17-cv-01243	Brown v. Boston Scientific Corporation
2:17-cv-01837	Allen v. Boston Scientific Corporation
2:17-cv-01845	Shiflet v. Boston Scientific Corporation
2:17-cv-01862	Faso et al v. Boston Scientific Corporation
2:17-cv-01900	Hauff et al v. Boston Scientific Corporation
2:17-cv-01925	Skalniak et al v. Boston Scientific Corporation
2:17-cv-01932	Peach v. Boston Scientific Corporation
2:17-cv-01938	Schroder v. Boston Scientific Corporation
2:17-cv-01939	Price v. Boston Scientific Corporation
2:17-cv-01940	Conley v. Boston Scientific Corporation
2:17-cv-01959	Lowrie v. Boston Scientific Corporation
2:17-cv-01977	Hardwick v. Boston Scientific Corporation
2:17-cv-01979	Dunford et al v. Boston Scientific Corporation
2:17-cv-01990	Hill-Sober et al v. Boston Scientific Corporation
2:17-cv-01996	Benson v. Boston Scientific Corporation

2:17-cv-02093	Pamensky Murray v. Boston Scientific Corporation
2:17-cv-02106	Wilson v. Boston Scientific Corporation
2:17-cv-02107	Ross v. Boston Scientific Corporation
2:17-cv-02110	Clark v. Boston Scientific Corporation
2:17-cv-02111	Busby v. Boston Scientific Corporation
2:17-cv-02202	Atwood v. Boston Scientific Corporation
2:17-cv-02243	Alvarado v. Boston Scientific Corporation
2:17-cv-02244	Speed v. Boston Scientific Corporation
2:17-cv-02416	Palmer v. Boston Scientific Corporation
2:17-cv-02417	Masterson v. Boston Scientific Corporation
2:17-cv-02443	Allex v. Boston Scientific Corporation
2:17-cv-02446	Blalock v. Boston Scientific Corporation
2:17-cv-02447	Casale v. Boston Scientific Corporation
2:17-cv-02448	Clark v. Boston Scientific Corporation
2:17-cv-02449	Cole v. Boston Scientific Corporation
2:17-cv-02450	Wallace v. Boston Scientific Corporation
2:17-cv-02459	Mallory v. Boston Scientific Corporation
2:17-cv-02461	Martin v. Boston Scientific Corporation

2:17-cv-02462	McSween v. Boston Scientific Corporation
2:17-cv-02467	Melrose v. Boston Scientific Corporation
2:17-cv-02470	Porter v. Boston Scientific Corporation
2:17-cv-02471	McFalls v. Boston Scientific Corporation
2:17-cv-02477	Pouncy v. Boston Scientific Corporation
2:17-cv-02481	Shepard v. Boston Scientific Corporation
2:17-cv-02483	Smith v. Boston Scientific Corporation
2:17-cv-02486	Daniell v. Boston Scientific Corporation
2:17-cv-02505	Cutlip v. Boston Scientific Corporation
2:17-cv-02508	Jeter v. Boston Scientific Corporation
2:17-cv-02524	Murphy v. Boston Scientific Corporation
2:17-cv-02525	Price v. Boston Scientific Corporation
2:17-cv-02527	Roark v. Boston Scientific Corporation
2:17-cv-02528	Saldivar v. Boston Scientific Corporation
2:17-cv-02531	Smith v. Boston Scientific Corporation
2:17-cv-02533	Southwood v. Boston Scientific Corporation
2:17-cv-02551	Solomon v. Boston Scientific Corporation
2:17-cv-02553	Spencer v. Boston Scientific Corporation

2:17-cv-02554	Stark v. Boston Scientific Corporation
2:17-cv-02562	Vincent v. Boston Scientific Corporation
2:17-cv-02566	Walker v. Boston Scientific Corporation
2:17-cv-02568	Welsh v. Boston Scientific Corporation
2:17-cv-02571	Wittenborn v. Boston Scientific Corporation
2:17-cv-02588	Adams v. Boston Scientific Corporation
2:17-cv-02589	Barnett v. Boston Scientific Corporation
2:17-cv-02590	Childress v. Boston Scientific Corporation
2:17-cv-02592	Dickeson v. Boston Scientific Corporation
2:17-cv-02596	McFolling v. Boston Scientific Corporation
2:17-cv-02597	Morgan v. Boston Scientific Corporation
2:17-cv-02598	Reid v. Boston Scientific Corporation
2:17-cv-02599	Reyes v. Boston Scientific Corporation
2:17-cv-02600	Rinaldi v. Boston Scientific Corporation
2:17-cv-02601	Woodard v. Boston Scientific Corporation
2:17-cv-02633	Pierson et al v. Boston Scientific Corporation
2:17-cv-02636	Walseth v. Boston Scientific Corporation
2:17-cv-02638	Buttke v. Boston Scientific Corporation

2:17-cv-02641	Harrison-Hood v. Boston Scientific Corporation
2:17-cv-02646	Gottfreid v. Boston Scientific Corporation
2:17-cv-02730	Black v. Boston Scientific Corporation
2:17-cv-02734	Henjum v. Boston Scientific Corporation
2:17-cv-02738	Martin v. Boston Scientific Corporation
2:17-cv-02739	Martinez v. Boston Scientific Corporation
2:17-cv-02742	Morales v. Boston Scientific Corporation
2:17-cv-02745	Shaw v. Boston Scientific Corporation
2:17-cv-02787	Stapf v. Boston Scientific Corporation